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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,205	08/08/2003	Terrence S. McGrath	6619-85-1CON	4081

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EXAMINER
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BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/637,205

Applicant(s)

MCGRATH ET AL.

Examiner

Retford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### **Claim Rejections-35 USC Sec. 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The relevant part of the factual inquiries set forth in *Graham v. John Deere & Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and content of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue
3. Resolving the level of ordinary skill in the pertinent art
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundgren et al (US 6, 127, 428) in view of Ladin et al (US 5, 792, 090) further in view of Kolta et al (US 6, 139, 876).

The claims are drawn toward a method of increasing tissue oxygenation in mammals by applying superoxygenated composition to tissue surface for a period of time in order to increase partial oxygen pressure ( $pO_2$ ) from 30-120%.

The claims are also drawn toward use of the above-mentioned method in humans, specifically on the skin in a medical situation or condition needing such treatment (e.g. bedsores, wounds, burns and ulcers); such condition caused by pathogen bacterial infection of mucosal

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surface or organ. The claims are further drawn toward the method wherein the composition comprises of 45-220 ppm oxygen at 34 degrees in a pharmaceutically acceptable vehicle or carrier such as microbubbles. According to the claims, the microbubbles have specified sizes (0.6 microns-10 microns) and the composition can be in the formulation as cream, lotion or gel.

Lundgren et al (Patent '428) discloses a method for increasing partial pressure of oxygen in tissues or organ by perfusion or agitation in medical situations or conditions such as myocardial ischemia (abstract, col 3, lin 60; col 4, lin 30-35; col 8, lin 15-34; col 16, lin 20-30 and col 21, lin 1-5). According to Lundgren et al, an increase in partial pressure of at least 5% over controls is achieved (col 21, lin 1-5 and table 3 at col 19). The method disclosed in Patent '428 achieves an increase in partial pressure of oxygen in tissues using microbubbles stabilized in protein coating and having size of about 3-6 microns (col col 10, lin 65 and col 7, lin 45-50) with oxygen entrapped therein (col 4, lin 45-60 and col 7, lin 55-65).

Patent '428 does not specifically disclose the use of the method for increasing partial pressure of oxygen in the or skin of humans in which there is a wound or burn or ulcer.

Ladin et al (Patent '090) disclose a method of increasing the partial pressure or oxygenation of in human skin surface; e.g. wound infection caused by pathogens; burns; ulcers and scalds—abstract, col 4, lin 15-30; col 5, lin 25-30; and col 10, lin 20-50 and col 11, lin 35.

Neither Lundgren nor Laden discloses the relationship between wound infection, wound healing, the increase in partial pressure of oxygen and the reasons or motivation for such application of a composition that can cause such increased tissue oxygenation.

Kolta et al (Patent '876) discloses wound infection by aerobic bacteria and the effects of gelatin with oxygen contained therein on treatment (col 1, lin 30-45; col 2, lin 15-35).

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According to Kolta et al, the increased partial pressure of oxygen in the gel applied at the wound site facilitates healing of wound (col 3, lin 15-30; col 4, lin 60 and col 7, lin 1-5).

One of ordinary skill in the art would have been motivated to make a composition suitable for delivery of oxygen to a wound site in order to increase partial pressure of oxygen at the wound or burn site such as disclosed by Lundgren et al where microbubbles have been used to increase tissue oxygenation of sites or organs. By applying such composition in the form of microbubbles or gel or lotion for delivery of oxygen to wound sites; one of ordinary skill would have expected to achieve increased tissue oxygenation and thereby facilitate the healing process at the wound or burn site as was achieved in the prior art (Patent '876, example 1 at col 6 and 7). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

### **Double Patenting**

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 3, 4, 5, 6, 7, 11, and 12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17, 18, 19, 20, 21, 22, 23, 25 and 26 of US Patent No. 6, 649,145.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims in the instant application, similar to those cited for the copending application, are drawn to a (a) a method of increasing tissue oxygenation in mammalian tissues such as skin tissue in man (b) the scope of the claims in the instant application, similar to those in the Patent '145 covers mammalian tissues in disease or in a medical condition such as in wounds, burns and ulcers (c) the claims in the instant application, similar to that in Patent '145 is directed toward increasing oxygenation in the tissues in order to overcome bacterial infection in the diseased tissues caused by anaerobic bacteria (d) a superoxygenated composition is used to increase oxygenation in the tissues in both the instant claims and the claims in Patent'145.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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